

REMARKS

**I. INTRODUCTION**

Claims 2, 10, 12, 14, 15, 18, 19, and 26 were previously canceled. Claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 remain under consideration in the present application.

**II. REJECTIONS UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN**

Claims 1, 3, 4, 6-9 and 27-30 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Publication No. 2003/0159615 by Anderson et al. (the "Anderson Publication") in view of U.S. Patent No. 6,565,532 issued to Yuzhakov et al. (the "Yuzhakov Patent"). (See Final Office Action, page 3). Claims 5, 11, 13, 16, 17, 20-23, and 25 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Anderson Publication in view of the Yuzhakov Patent and further in view of U.S. Patent No. 5,836,998 issued to Mueller et al. (the "Mueller Patent"). (See *id.*, p. 10). Claim 24 stands finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Anderson Publication in view of the Yuzhakov Patent and the Mueller Patent, and further in view of U.S. Publication No. 2002/0091311 of Eppstein et al. (the "Eppstein Publication"). (See *id.*, p. 12).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, "if the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology*,

*Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, \*21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, “the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The Anderson Publication relates to microparticles that can be implanted in the dermis to form permanent tissue markings, such as tattoos, where such markings may later be removed by application of energy, such as optical radiation. (See Anderson Publication, Abstract, and paras. [0016], [0133], and [0134]).

The Yuzhakov Patent relates to microneedle arrays that can be used to apply markings to the epidermis of the skin that do not enter the dermal layer. (See Yuzhakov Patent, Abstract; col. 3, lines 54-59; col. 8, lines 1-14; and col. 41, lines 36-45).

The Eppstein Publication describes methods and apparatus for increasing permeability of a biological membrane using a pyrotechnic charge to form openings

therein. (See Eppstein Publication, Abstract, and paragraph [0041]). The methods and apparatus of Eppstein can be used with a substrate containing pigments, where the pigments are forced into the skin by the charge to form a tattoo. (*Id.*, para. [0044]).

The Mueller Patent describes the use of a stencil for body art whereby a stain is applied to a predetermined epidermal area delineated by the stencil. (See Mueller Patent, col. 1, line 65-col. 2, line 11).

Applicant respectfully asserts that the Anderson Publication, either taken alone or in a purported combination with the Yuzhakov Patent (which would not be the case), fails to disclose, teach, or suggest the subject matter recited in independent claims 1 and 11 and the claims which depend from them, for at least the reasons set forth below.

Independent claim 1 recites a method for fractional wounding of skin that includes, *inter alia*, applying at least one chromophore to a predetermined area of skin, where a specific pattern of the chromophore or a mask thereon **corresponds to a desired pattern of fractional wounding of the skin**, and applying electromagnetic radiation to the predetermined area of skin **so as to produce or generate a plurality of thermally damaged regions (or regions of thermal injury) in at least an epidermal portion of the skin based on an interaction between the at least one chromophore and the electromagnetic radiation.**

The Examiner acknowledges that the Anderson Publication describes deposition of microparticles into the dermis, and admits that this publication fails to

teach, suggest or disclose any method in which **a plurality of thermally damaged regions** (or regions of thermal injury) of tissue are generated or produced **in at least an epidermal portion of the skin** based on an interaction between one or more chromophore(s) and an electromagnetic radiation, as explicitly recited in independent claim 1. (See Final Office Action, page 4). The Examiner contends, however, that the epidermal layer would be fractionally damaged by the application of the chromophores. (*Id.*) Applicant respectfully points out that such alleged “fractional damage” to the epidermal layer, if it were caused by application of chromophores to the dermis, would be mechanical in nature and distinct from the **thermally damaged regions generated based on an interaction between the at least one chromophore and the electromagnetic radiation**, as recited in independent claim 1.

The Anderson Publication further describes only the generation of skin markings by providing microparticles containing chromophores in the **dermis** region of skin tissue, where such otherwise permanent markings can be removed by exposing the microparticles to appropriate energy, such as optical energy. (See Anderson Publication, paras. [0005], [0012], [0133], and [0134]). For example, the Anderson Publication states, in part, the following:

“[t]issue markings in skin **must be properly placed to provide permanent markings**. Skin is composed of the outermost epidermis, generated by the constantly dividing stratum basale, and the underlying dermis. Dermal cells, such as fibroblasts, mast cells, and others, which do not generally replicate, are located within a resilient proteinaceous matrix. **It is the upper dermis, below the stratum basale, into which the microparticles are implanted to provide a tissue marking** (such as a tattoo).” (*Id.*, para. [0133]; **emphasis added**).

Thus, the Anderson Publication explicitly requires that such markings must be placed below the stratum basale to be permanent, and thereby be removable only by exposure to energy. The Anderson Publication thereby acknowledges the *well-known biological effect* that markings placed in the epidermal layer, above the stratum basale, will not be permanent and will gradually disappear as the epidermal cells are continuously sloughed off. (See, e.g., Yuzhakov Patent, col. 42, lines 3-10). The Anderson Publication does not describe, and in fact teaches away from, application of the colored microparticles to the epidermal layer to form markings and subsequent removal of such microparticles by exposure to energy, at least in part because such epidermal markings would not be permanent and would disappear by themselves without exposure to energy such as optical energy.

The Anderson Patent clearly does not teach or suggest a method for fractional wounding, as recited in independent claim 1. Applicant notes that the Anderson Publication teaches away from damaging the skin tissue when exposing the microparticles to energy such as optical energy. For example, the Anderson Publication describes the use of fluencies that are “well tolerated by the skin” and that “higher laser fluencies that do not injure the tissue can be used...” (*Id.*, para. [0150]; **emphasis added**). The Anderson Publication further notes that “Ideally, short, powerful light pulses are absorbed specifically by tattoo pigment particles with little or no absorption by surrounding tissue, thereby causing the particles of pigment to break apart with minimal damage to neighboring skin structures.” (*Id.*; **emphasis added**). Accordingly, Applicant asserts that the Anderson Publication teaches away from

generating **any** thermal damage in the skin tissue, and therefore it does not teach or suggest the formation of a **desired pattern of fractional wounding of the skin**, as explicitly recited in independent claim 1.

The Examiner alleges that independent claim 1 and claims 3, 4, 6-9 and 27-30 that depend therefrom are unpatentable in view of a purported combination of the Anderson Publication with the Yuzhakov Patent. (See Final Office Action, page 3). The Anderson Publication is directed towards **permanent**, removable tissue markings that are formed by introducing microparticles into the **dermis**. (See Anderson Publication, Title; and paras. [0001], [0133], [0134], and [0143]). In contrast, the Yuzhakov Patent describes the use of microneedle arrays, *inter alia*, to introduce substances, such as ink or pigment, into the **epidermal** layer to produce semi-permanent markings that would disappear from the skin after a time period. (See Yuzhakov Patent, Abstract; col. 3, lines 54-59; col. 8, lines 1-14; col. 41, lines 36-45; and col. 42, lines 3-10).

The Examiner alleges that the Anderson Publication and the Yuzhakov Patent are both directed to “tattoos created by damaging and implanting active agents into layers of the skin.” (See Final Office Action, page 5). However, Applicant notes that such tattoos are not provided in a **desired pattern of fractional wounding** that is used to produce a plurality of **thermally damage regions in at least an epidermal portion of the skin**, as recited in independent claim 1. Any thermal damage produced as described in the Anderson Publication is incidental, minimal, and undesirable, as noted above. Further, the Yuzhakov Patent fails to describe any thermal damage of

skin at all, and the "damaging" cited by the Examiner is merely incidental mechanical damage to the epidermal skin layer caused by penetration of the microneedles. Accordingly, Applicant asserts that one of ordinary skill would not look to the Anderson Publication to produce a plurality of **thermally damage regions** in a **desired pattern of fractional wounding**, as recited in independent claim 1, and the Yuzhakov Patent does not cure this deficiency, as it fails to even mention the concept of thermal damage of skin tissue.

The Anderson Patent explicitly describes the placement of microparticles in the dermis, below the stratum basale, to form permanent skin markings that are removable only by exposure to energy. In contrast, contrary to the disclosure of the Anderson Patent, the Yuzhakov Patent describes the use of microneedle arrays to introduce particles or pigments into the epidermis to produce semi-permanent markings that will disappear after a time period, such that the exposure to energy to remove such markings (as described in the Anderson Publication) is unnecessary. (See Yuzhakov Patent, col. 42, lines 3-10). One of ordinary skill in the art would certainly not look to either the Anderson Publication or the Yuzhakov Patent to purposely generate regions of thermal damage in a desired pattern of fractional wounding, much less combine them to do so. Accordingly, Applicant respectfully asserts that one having ordinary skill in the art would be taught away from producing or generating thermally damaged regions or regions of thermal injury of tissue in a an epidermal portion of tissue based on the explicit disclosure of the Anderson Patent and the understanding in the art. In addition, it is respectfully asserted that the alleged



combination of the Anderson Publication and the Yuzhakov Patent relied on by the Examiner represents impermissible hindsight, and that it fails to establish a *prima facie* case of obviousness.

Independent claim 11 recites, *inter alia*, applying to a region of skin a chromophore and a mask having a specific pattern corresponding to a **desired pattern of fractional wounding**, and applying electromagnetic radiation to generate regions of thermal injury **in an epidermal portion of the skin** based on an interaction between the electromagnetic radiation and the chromophore. The purported combination of the Anderson Publication with the Yuzhakov Patent, even if so combined (which Applicant believes to be improper) fails to render obvious this recited subject matter, for at least the reasons described above with respect to claim 1. The Mueller Patent relied on by the Examiner, which describes the use of a stencil to form a pattern of stain on the skin, fails to cure this deficiency. Accordingly, Applicant respectfully traverses the rejection of claims 5, 11, 13, 16, 17, 20-23, and 25 based on a purported combination of the Anderson Publication, Yuzhakov Patent, and Mueller Patent.

Applicant further asserts that claim 24, which depends indirectly from claim 1, is not obvious in view of the purported combination of the Anderson Publication and the Yuzhakov Patent for at least the same reasons provided above with respect to claim 1, and that the Epstein Patent fails to cure this deficiency.

Accordingly, withdrawal of the rejections of all pending claims under 35 U.S.C. § 103(a) is respectfully requested.

**IV. CONCLUSION**

In light of the foregoing, Applicant respectfully submits that all arguments raised in the Final Office Action have been addressed and that all pending claims 1, 3-9, 11, 13, 16, 17, 20-25, and 27-32 are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner is invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

Respectfully submitted,

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